UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,695	06/10/2005	Jin Woo Park	11617-004	6982

20583 7590 01/25/2007

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,695	PARK ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *8-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Release is acknowledged of applicants' IDS (filed on 20 March 2006) and response to restriction requirement (filed on 24 October 2006).

* * * * *

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 24 October 2006 is acknowledged. The traversal is on the grounds that: (1) the reference used by examiner to teach the common technical feature of the instant application discloses a single granulation process (as interpreted by applicants) while the instant application recites a dual granulation process; and (2) the reference discloses a multiple unit dose. This is not found persuasive because the common technical feature cited in the previous Office action is a sustained-release preparation prepared from double granules, not the granulation process. Furthermore, applicants do not claim either single or multiple unit dosage forms. Thus, examiner respectfully submits that applicants' argument is outside the scope of the common technical feature cited.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 24 October 2006.

* * * * *

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (b) as follows: Applicant failed to provide an English translation of the foreign application Korea 10-2003-0004521. As such, the priority date of the instant application is interpreted as 19 January 2004, which is the date of PCT/KR04/00092.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (US 2004/0022848).

Kikuchi et al. teach a pharmaceutical preparation obtained by primary granulation of a drug and a hydrophobic additive (waxy substance) (see paragraphs 0061 and 0062), followed by secondary granulation of the obtained granules by wet granulation using a hydrophobic wet granulation material (*see* paragraph 0065).

Kikuchi et al. explain that this technique is beneficial in taste masking (*see* paragraph 0066).

The Kikuchi et al. reference differs from the instant application in that it does not teach a melt granulation technique for primary granulation. However, the granulation

techniques are not essential to a determination of patentability of the composition disclosed in the claim. As explained by the court in *In re Thorpe et. al.* (CAFC 1985) 779 F2d 695, "A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim."

Furthermore, although Kikuchi et al. do not explicitly teach a sustained release preparation, properties are the same when the structure and composition are the same. Here, the instant application and the prior art both disclose a primary granulation product containing a hydrophobic additive which is subject to secondary granulation with a hydrophobic wet granulation material. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a pharmaceutical preparation obtained by primary granulation of a drug followed by secondary granulation of the granules obtained from primary granulation, as taught by Kikuchi, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful in taste masking, as explained by Kikuchi, et. al.

*

2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (US 2004/0022848) in view of Oshlack et al. (US 2002/0102302).

Kikuchi et al. teach a pharmaceutical preparation (*see* above). The Kikuchi et al. reference differs from the instant application in that it does not teach the specific drug and excipients claimed.

Oshlack et al. teach a sustained release composition (*see* paragraph 0014) comprising:

- the tramadol of instant claim 3 (*see* paragraph 0014);
- the waxes of instant claim 4 (*see* paragraph 0056);
- the beeswax of instant claim 5 (*see* paragraph 0056);
- the hydrogenated vegetable oil of instant claim 6 (*see* paragraph 0056); and
- the additives of instant claim 7 (*see* paragraph 0021).

Oshlack et al. explain that the combination of these ingredients into one preparation is beneficial for the sustained treatment of pain (*see* paragraph 0013).

While Oshlack et al. do not explicitly teach all the percentages of instant claim 2, examiner respectfully submits that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955).

Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a sustained release pharmaceutical preparation comprising tramadol and using two granulation processes, as taught by Kikuchi et al. in view of Oshlack et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful in the sustained treatment of pain, as explained by Oshlack, et. al.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/572,326 ('326). Although the conflicting claims are not identical, they are not patentably distinct from each other because '326 claims a sustained release pharmaceutical composition prepared by a first granulation method followed by a second granulation method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

☆ ☆ ☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***

HUMERA N. SHEIKH
PRIMARY EXAMINER
TC-1600